REMARKS

Formal Matters

The Examiner has objected to claims 23 and 42-44 based on certain informalities. Specifically, the Examiner has objected to claims 23, 42 and 44 on the basis that the word "chymotrypsin" is misspelled. The Examiner has also objected to claim 43 on the basis that the word "enzymes" was omitted. Applicant has amended claims 23 and 42-44 to correct these informalities and respectfully requests that this objection now be withdrawn.

New Matter Rejection

Claim 44 was rejected under 35 U.S.C. §112, first paragraph, for the reasons set forth on page 2 of the Office Action. Specifically, the Examiner has indicated that the specification does not provide a basis for a method of treating protein deficiency in an individual having an autistic disorder with digestive enzymes. Applicant respectfully disagrees with the claim rejection.

Paragraph 37 of the specification states as follows: "...the pancreas secretes the enzyme trypsin in an inactive form trypsinogen. The trypsinogen is converted to trypsin in the small intestines. In an environment where the pH is 6.5 or greater, the trypsin catalyzes the formation of chymotrypsinogen to chymotrypsin. These enzymes are essential for the digestion of protein. In the absence of protein digestion, the amino acids necessary for the growth and development of individuals are absent."

A lack of protein digestion would be a direct consequence of low fecal chymotrypsin. Since chymotrypsin is the only digestive enzyme that cleaves only essential amino acids, it would be clear to someone skilled in the art that the dearth of essential amino acids would produce a protein deficiency in these individuals. As a pool of amino acids are necessary for the body to build other proteins, a lack of protein digestion, especially one characterized by a low level of chymotrypsin, would therefore lead one to understand that a protein deficiency is present in these individuals.

Double Patenting Rejection

The Examiner has rejected claims 23, 42 and 43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,632,429. Applicant reserves the right to file a terminal disclaimer to overcome this rejection prior to allowance of the present application.

Rejection under 35 USC §112

Claims 23-35 and 42-43 were rejected under 35 U.S.C. §112, first paragraph, for the reasons set forth on page 4-5 of the Office Action. Specifically, the Examiner has indicated that the specification does not provide enablement for claims to a method for treating autistic individuals having an "abnormal" or increased fecal chymotrypsin level. Applicant respectfully disagrees with this rejection.

Paragraph 41 of the specification states as follows: "...normal levels of chymotrypsin are deemed to lie above 8.4 U/gram, whereas pathologically abnormal levels are deemed to lie below 4.2 U/gram. In addition, chymotrypsin levels between 8.4 U/gram and 4.2 U/gram are considered equivocal, and further testing of the individual's fecal chymotrypsin levels over a period of time should be performed."

It is understood by those skilled in the art that abnormal fecal chymotrypsin levels are characterized by low or decreased levels of fecal chymotryspin. The fecal chymotrypsin test (FCT) test which has been utilized for over 40 years as a standard medical test, has no upper limit of normal, thus all levels above 8.4 are considered normal.

Claim Rejection – 35 U.S.C §103

The Office has quoted the statute from 35 USC 103(a), which is referenced herein. The Office has rejected claims 23-35 and 42-43 as being unpatentable over Beck et al. (US 6,020,310) and Sipos (US 4,079,125). Applicant has carefully considered the Office rejections and respectfully submits that the amended claims, as supported by the arguments herein, are distinguishable from the cited references.

According to the MPEP §2143.01, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found in either in the references themselves or in the knowledge generally available to one of ordinary skill in the art."

A useful presentation for the proper standard for determining obviousness under 35 USC §103(a) may be illustrated as follows:

1. Determining the scope and contents of the prior art;
2. Ascertaining the differences between the prior art and the claims at issue;
3. Resolving the level of ordinary skill in the pertinent art; and
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

According to the Office, Beck discloses digestive enzyme deficiencies in children with autistic behavior. However, the Examiner does indicate that Beck does not explicitly mention treating autism having digestive enzyme deficiencies with digestive enzymes. While Beck discloses that a certain subset of children with autism have gastrointestinal dysfunction, there are no values of the measured chymotrypsin in the '310 patent. Further, the Horvath publication entitled "Improved Social and Language Skills After Secretin Administration in Patients with Autistic Spectrum Disorder", *J. Assoc. for Academic Minority Physicians* 9(1):1998, pp. 9-15 states that the enzyme activities of all the children examined were within normal limits. Further, the three children who were outlined both in the '310 patent and in the Horvath paper had normal chymotrypsin levels (one child did not have the levels drawn). Therefore, it would not clear to one of ordinary skill in the art that low levels of fecal chymotrypsin or the administration of digestive enzymes would be beneficial to a child with autism.

According to the Office, Sipos teaches digestive enzyme-containing compositions, which are capable of withstanding hours of exposure to gastric fluids while

protecting the biological activity of the enzymes, that the principal active agents in the composition are enzymes, including chymotrypsin, that the total amount of the composition required to be administered to an enzyme deficient patient will vary with the severity of the condition and the amount of food ingested, and that the composition is administered with each meal.

The Sipos patent 4,079,125 is directed to a composition of matter. This patent is not directed at giving digestive enzymes to an individual based on low chymotrypsin levels, nor is it based on any clinical patient work. As all medication directed at treating children is dose dependent upon weight, it would be normal for any and all medicines to be directed in that way, save for vaccines which are not directed to be administered as dose dependent upon weight.

At the time of the Sipos invention, the digestive enzymes were directed toward administration to those with cystic fibrosis and pancreatitis. Never had the administration of digestive enzymes to those with autism been contemplated by this patent. Further, while determination of dosages would be in the composition of matter, it was not contemplated in Sipos directing those toward autism.

It is known to those skilled in the art that, prior to Applicant's invention, digestive enzymes were only allowed by the Food and Drug Administration (FDA) for administration to those with cystic fibrosis, and chronic pancreatitis. Further, the lipase portion of the digestive enzyme was specifically necessary for cystic fibrosis (CF), and the amylase portion was specifically necessary for those with chronic pancreatitis. Nowhere, prior to Applicant's invention, was the need for the protease portion of the enzyme composition, anticipated for autism or for any other disease, syndrome or symptom. The Sipos composition of matter patent protects his formulation, and never was that formulation anticipated for autism or other conditions.

Obviousness cannot be established by combining prior art to produce the claimed invention absent some teaching of suggestion supporting the combination. The mere fact

that the prior art may be modified in the manner suggested by an examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

The Board of Patent Appeals and Interferences (BPAI) continues to reverse Examiners that cannot explain "why a person of ordinary skill in the art would have found it obvious to combine the references in the manner proposed by the Examiner." Furthermore, the Applicant notes that none of the references specifically recognized the advantages discussed in the present application.

Applicant respectfully disagrees that it would have been prima facie obvious for one with ordinary skill in the art to combine the inventions of Beck et al. and Sipos in order to formulate claims 23-35 and 42-43 of the present invention. Applicant respectfully submits that a person with ordinary skill in the art would not have looked to the Beck et al. and Sipos references as these references do not teach treating autistic individuals having digestive enzyme deficiencies and low, abnormal chymotrypsin levels with digestive enzymes.

Conclusion

For the reasons stated above, Applicant respectfully submits that the rejections of claims 23-35 and 42-44, as amended, are not proper and respectfully requests that the Office withdraw these rejections.

Telephone Interview

Present Office policy places great emphasis on telephone interviews initiated by the examiner. For this reason, it is not necessary for an attorney to request a telephone interview. Examiners are not required to note or acknowledge requests for telephone calls or state reasons why such proposed telephone interviews would not be considered effective to advance prosecution. However, it is desirable for an attorney to call the examiner if the attorney feels the call will be beneficial to advance prosecution of the application. MPEP §408.

Applicant believes the above amendments and remarks to be fully responsive to the Office Action, thereby placing this application in condition for allowance. No new matter has been added. Applicant requests speedy reconsideration, and further requests that Examiner contact its attorney by telephone, facsimile, or email for quickest resolution, if there are any remaining issues.

Respectfully submitted,

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